U.S. Environmental Protection Agency
Office of Research and Development

BOARD OF SCIENTIFIC COUNSELORS
HUMAN HEALTH SUBCOMMITTEE

Conference Call Summary
February 15, 2005
12:00 noon–2:00 p.m. EST

Welcome

Ms. Virginia Houk (EPA/NHEERL), the Designated Federal Officer (DFO) for the Human Health Subcommittee, asked the members to introduce themselves:

- James Klaunig from Indiana University is a toxicologist and is chair of the subcommittee.
- James Clark from Exxon Mobil Research and Engineering Company, vice-chair of the subcommittee, is an environmental toxicologist and a member of EPA's Board of Scientific Counselors (BOSC).
- Timothy Buckley from the Department of Environmental Sciences at the Johns Hopkins School of Public Health is an exposure assessor with an interest in environmental carcinogens and the use of biomarkers for assessing exposures.
- Elaine Symanski from the Division of Environmental and Occupational Health Sciences at the University of Texas School of Public Health is an exposure assessor with an interest in developing quantitatively based methods to evaluate exposures to both environmental and occupational contaminants.
- Joseph Landolph is a professor of molecular microbiology and immunology pathology at the University of Southern California School of Medicine's Norris Comprehensive Cancer Center. His research interests include the molecular mechanisms by which nickel, chromium, and arsenic compounds and PAH cause morphological and neoplastic transformation and carcinogenesis.

Administrative Procedures

Ms. Houk thanked the subcommittee members for their attendance and interest. She began her presentation by explaining the functions of the BOSC. As a federal advisory committee, the BOSC provides independent, scientific peer review and advice to EPA's Office of Research and Development (ORD). The Human Health Subcommittee was established by the BOSC Executive Committee to review ORD's Human Health Research Program. The subcommittee has been asked to respond to charge questions and to provide a report to the BOSC Executive Committee. The Executive Committee will review the subcommittee's report, revise it as necessary, and submit it to ORD. Whereas the role of the BOSC is to provide advice and recommendations to ORD, the rights of decision-making and program implementation remain with EPA.

This is the subcommittee's first conference call, a second call is planned for February 24, and a face-to-face meeting is scheduled for February 28 to March 2 in Research Triangle Park, North Carolina. Additional meetings can be scheduled if necessary. It is anticipated that a conference call in March or early April will follow the face-to-face meeting.

The DFO serves as the liaison between the subcommittee and EPA and is responsible for ensuring that the subcommittee and its meetings comply with the Federal Advisory Committee Act (FACA). Ms. Houk explained some relevant FACA rules and procedures:

- All meetings involving substantive issues, whether in person, via telephone, or by e-mail, are open to the public. This rule applies to all group communications that include at least half of the subcommittee members. Issues that are solely administrative or preparatory in nature are exempt from this requirement.
- A *Federal Register* notice must announce all meetings and calls 15 calendar days in advance.
- The DFO must approve the agenda and attend all meetings and calls.
- Meeting minutes must be certified by the chair within 90 days of the meeting.
- All advisory committee documents must be made available to the public.
- This subcommittee provides advice to the BOSC Executive Committee, not to ORD.

The DFO has worked with EPA officials to ensure that all appropriate ethics regulations are satisfied. Each subcommittee member has filed a standard government financial disclosure report. These reports are reviewed by the Deputy Ethics Officer of ORD's Office of Science Policy and the DFO in consultation with the Office of General Counsel to ensure all ethics requirements are met. In addition, subcommittee members are required to complete annual ethics training.

After describing the process for agenda development and public comment, Ms. Houk noted that the public docket for this subcommittee's meetings can be accessed at www.epa.gov/edocket (ORD-2005-0002).

The charge presented to the Human Health Subcommittee by the BOSC Executive Committee consists of questions addressing a broad range of topics, including both management and scientific issues. The questions are intended to be both prospective and retrospective in nature. The subcommittee's review will be shaped by the spectrum of expertise possessed by the subcommittee members. Ms. Houk explained the purpose of the conference call—to review and revise or approve the proposed poster assignments, make writing assignments for the draft report, and develop an outline for the draft report. The subcommittee will produce a draft report following the face-to-face meeting and a draft final report following the March or April conference call. The draft final report will be presented to the BOSC Executive Committee for its deliberation.

Dr. Clark pointed out that in addition to science, the BOSC focuses on management, coordination, communications, planning, and outreach. He described the background materials distributed to the subcommittee members before the call, including the Human Health Multi-Year Plan (MYP) and the Human Health Research Strategy. The charge questions concern the

relevance, quality, performance, and scientific leadership of the Human Health Research Program.

Explanation of Documentation

Dr. Hugh Tilson, the Acting National Program Director for Human Health Research at EPA, referred to the documentation provided to the subcommittee members (a three-ring binder containing 13 sections and a CD as well as 3 additional documents, namely the Human Health Research Strategy, the Human Health MYP, and report of a STAR grantees symposium). These background materials are meant to help the subcommittee make judgments about how to respond to the charge questions.

Dr. Tilson explained the four research and development investment criteria: relevance, quality, performance, and scientific leadership. Relevance concerns the contextual framework by which to identify and prioritize research and deliver products to stakeholders. It also involves a relationship to the Agency's mission. Quality concerns how the Agency deals with peer review of outputs and allocation of resources to high-priority research areas. Performance involves a focus on key scientific questions, a process to track outputs over time, and progress toward meeting long-term goals (LTGs). Scientific leadership is related to advancing the state of knowledge in disciplines related to key scientific questions.

The background materials (as listed on the provided PowerPoint slides) include (1) the Human Health Research Strategy 2003, (2) Human Health MYP 2003, (3) ORD overview materials, (4) thematic summaries, (5) a bibliography organized by LTGs, (6) biosketches of participants, and (7) a summary of the STAR Progress Review Workshop. A miniversion of poster abstracts and hardcopies of oral presentations will be provided at the review meeting.

Dr. Landolph asked about the influence of the Science Advisory Board (SAB) review, and Dr. Tilson responded that the reviewers' comments were incorporated into the Human Health Research Strategy document, which was used as the basis for the MYP. The MYP is an implementation document.

Dr. Symanski asked about the timeframe covered by the subcommittee's review. Dr. Tilson responded that the review is retrospective and prospective. It focuses on the period from 1999 to the present. The prospective aspect of the review involves future directions of the program.

Dr. Clark mentioned the difference between the SAB and the BOSC reviews. The former focused on prospective planning, and the BOSC review covers that as well as the execution of the plan.

In response to a question from Dr. Klaunig about the LTGs and the program's future direction, Dr. Tilson explained that the area of susceptible subpopulations currently involves children and the elderly and focuses on asthma. Is another subpopulation missing from consideration? Are we asking the right questions about children and the elderly?

Dr. Clark asked how Dr. Tilson interacts with the laboratory center directors and senior managers in ORD. Dr. Tilson explained that the program originated with a steering group that included representatives from each of the centers and laboratories as well as the program and regional offices. The steering group developed the LTGs, the key research questions, and topics to be addressed. There has been an effort to generate grassroots participation by the centers and laboratories. One of the purposes of the program review is to try to determine the integrated, multidisciplinary nature of research in ORD regarding human health and how that work might influence or inform other problem-driven areas, such as endocrine disruptors, pesticides, and drinking water. Another concern involves the integrated nature of the intramural and extramural programs. The multidisciplinary research program is based on a paradigm that involves movement from source to exposure to dose to effect. The objective is to reduce the uncertainty of the links associated with each component in the exposure-to-effect paradigm.

EPA Programmatic Issues

Ms. Jennifer Robbins from the ORD Office of Resources Management and Administration presented an overview of the Office of Management and Budget's (OMB) Performance Assessment Rating Tool (PART) and described the investment criteria for research and development (R&D). PART evaluates program effectiveness in four areas: purpose and design, strategic planning, program management, and program results. It consists of approximately 30 questions in these four areas as well as a measures tab that asks programs to present their long-term annual outcome and output measures. Programs receive a numerical score and a rating ranging from "effective" to "ineffective" with a separate category for "results not demonstrated." PART is applied to all federal programs across the government.

In response to a question from Dr. Buckley about the PART scoring process, Ms. Robbins explained that a program submits a self-assessment to OMB. OMB assigns an examiner to evaluate the evidence and self-assessment, engage in discussions, and determine the program's score. Dr. Symanski asked whether the outcomes are developed before the evaluation or are part of the evaluation. Ms. Robbins explained that OMB provides feedback about provided outcomes.

After Ms. Robbins gave a summary (details provided on the PowerPoint slides) of the history of ORD's PART status, she described the R&D investment criteria developed by OMB and the Office of Science and Technology Policy (OSTP) to warrant continued or increased funding. The criteria are quality, relevance, and performance. R&D investments must be clearly planned to be relevant to national priorities, agency missions, and customer needs. The programs also must maximize the quality of the research in which they invest. In addition, R&D programs must demonstrate performance by setting annual and LTGs and demonstrating progress toward outcomes. OMB and OSTP outline the requirements in a five-page memo, and the criteria are incorporated into the R&D-specific PART questions to which research programs must respond.

After presenting more detailed information about each criterion (details provided on the PowerPoint slides), Ms. Robbins addressed a question about scientific leadership. Scientific leadership is not one of the investment criteria defined by OMB and OSTP; instead, it is subsumed under quality and performance. The charge questions target four criteria, including scientific leadership.

Ms. Robbins explained the ORD logic model, which shows the flow from resources and research activities to long-term outcomes. Products of the research program are transferred to clients who use the products to contribute to or achieve intermediate and long-term outcomes. Independent expert evaluation focuses on the transfer point at which clients influence the achievement of environmental or human health outcomes. The evidence is the MYPs, synthesis products, performance data, and client feedback. The sphere of influence includes ORD, EPA clients, and the Agency's partners. ORD has direct control over how it manages its resources and activities to produce high-quality outputs. ORD has direct influence over clients who use the information. Agencies have an indirect impact on achieving environmental and health outcomes. ORD programs can be accountable for research contributions that strengthen environmental decisions and enable clients to achieve short-term outcomes. ORD does not argue, however, that research programs should be held accountable for the actual achievements of environmental or health outcomes, such as reducing pollution. ORD's goals and measures are focused on client and customer use of ORD products. Through PART, agencies must submit evidence that supports a research program's design and purpose (20% of total score), strategic planning (10% of total score), management (20% of total score), and results (50% of total score).

In conclusion, Ms. Robbins stated that the effective articulation of program design offers ORD its best opportunity to achieve its goals, demonstrate the value of its efforts, and maintain (or increase) support and funding for EPA R&D programs.

Dr. Tilson stated that a presentation during the next conference call will expand on the logic model information provided by Ms. Robbins. Dr. Clark noted that the subcommittee will spend a great deal of time discussing outputs and outcomes in relation to ORD.

Preparation for the Face-to-Face Meeting

Before the discussion of the various topics under this section of the agenda, Dr. Buckley asked Ms. Houk to comment on the thought and strategy that went into the formulation of the subcommittee, in particular, representation from academia and industry and across scientific disciplines. Ms. Houk explained that, based on the depth and breadth of the human health program, core areas of expertise were identified, including toxicology, epidemiology, exposure modeling, and physiologically based pharmacokinetic (PBPK) modeling. Lists of potential members then were generated according to each of the areas of expertise. The names came from various sources, such as scientific society memberships and clients. The subcommittee was formed on the basis of areas of expertise and experience within certain fields, including academia, industry, and government organizations. Dr. Hal Zenick (EPA/NHEERL) mentioned the complications that arise from conflict-of-interest issues. Dr. Clark added that the BOSC envisioned a seven- to eight-person subcommittee.

Review of the Agenda

Dr. Klaunig described the format and agenda for the face-to-face meeting. There will be a short presentation on each of the LTGs, followed by poster sessions and panel discussions. Dr. Clark added that the meeting will be organized to facilitate the production of a report. On the last day

of the meeting, testimonials will be presented on the relevance of the Human Health Research Program, and a discussion and work session will be held to develop an oral report to be presented at the end of the meeting.

Poster Review Process and Assignments

Within the proposed poster assignments are primary and secondary reviewers, who will give feedback to the lead writer for each LTG about the take-home message regarding the charge. The subcommittee was asked to decide whether the primary reviewers would contribute to the writing on each LTG or whether individuals should be assigned to the writing tasks. Ms. Houk cautioned that there are 17 posters for LTG 2 and the primary and secondary reviewers are the same for both topics under that LTG. Should that assignment be spread out among other subcommittee members? It was decided that Drs. Klaunig and Clark and Ms. Houk will assign additional reviewers to the LTG 2 posters.

Writing Assignments

Dr. Klaunig asked whether the primary poster reviewers should be aligned with the lead writer for writing assignments. It was decided that the primary reviewers of the poster session will help the lead writer on that particular LTG. Dr. Klaunig will make assignments for summarizing the testimonials. Drs. Symanski (LTG 4) and Buckley (LTG 3) agreed to accept their writing assignments.

Draft Report Outline

Dr. Klaunig referred to the BOSC Program Review document provided by Ms. Houk and described its format. He called attention to the difference between the outline topics and the charge questions, especially the absence of the topics of quality and performance, and noted that the charge questions are implied in the subcategories. Dr. Clark added that the report should follow the charge questions for each of the LTGs. Progress implies performance and quality. The charge questions can be integrated into the outline topics.

Ms. Houk stated that a subgroup would be composed of three individuals (the lead writer and two others). It was decided that at the face-to-face meeting, meeting space would be provided for small working groups to discuss writing assignments.

Identification of Additional Information Needs

Subcommittee members were encouraged to read the MYP and the Research Strategy.
Dr. Symanski asked whether the posters will be science based or whether they will attempt to answer some of the questions posed in the charge. Dr. Clark responded that the posters will be programmatic as well as scientific. Dr. Tilson added that the posters will demonstrate the scientific and programmatic aspects of the question, along with the approach, outcome, impact, and future direction of the program. Because various programs have different starting dates and, therefore, different outcomes at the time of review, the presenters have been encouraged to comment on that variability. Ms. Houk described the poster miniatures. The subcommittee

members agreed that the poster miniatures should be made available to them at the hotel on the Sunday evening before the face-to-face meeting.

Dr. Buckley asked what the subcommittee members are expected to accomplish before the face-to-face meeting. Dr. Klaunig responded that as much writing as possible should be done before the meeting. The subcommittee members also should read the background materials and are permitted to engage in discussions if only three or fewer people are involved.

Dr. Symanski raised a question about addressing the answers to the charge questions in the report. The response was that the questions do not have to be restated and then addressed. Ms. Houk reiterated that the charge questions should be addressed or answered, but an itemization of the questions is not necessary. The executive summary, which will be written by Drs. Klaunig and Clark, will consider the program as a whole.

Next Conference Call

The next conference call is scheduled for Thursday, February 24, 2005, from 12 noon to 2 p.m. EST.

In response to Ms. Houk's call for public comments, no member of the public came forward to make any comments. The meeting adjourned at 1:50 p.m.

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